Amend Trial (NCI ID: NCI-2016-00003)

− Collapse All

Amendment Details

Amendment Number:* 32432

Amendment Date:* 07-Jun-2016

Trial Identifiers

Study Source:* National

Lead Organization Trial Identifier:* Lorem ipsum dolor sit amet, consectetur adipiscing

NCI ID: NCI-2016-00003

Other Trial Identifier: Protocol ID Type | Protocol ID | -Select a Protocol ID T | + Add

Protocol ID Type	Protocol ID
Other Identifier	4353

Trial Details

Official Title:* Lorem ipsum dolor sit amet, consectetur adipiscing elit. Sed a ligula urna. Proin felis ex, interdum feugiat sodales ut, sodales a mauris. Donec molestie, quam vitae

Phase:* I

Pilot?* ◉ No ○ Yes

Research Category:* Interventional

Primary Purpose:* Treatment

Secondary Purpose: Ancillary-Correlative

Accrual Disease Terminology:* SDC

Lead Organization/Principal Investigator

Lead Organization:* Boston Medical Center | Search Organizations

Principal Investigator:* Lee, James | Search Persons

Sponsor

Sponsor:* Boston Medical Center | Search Organizations

Data Table 4 Information

Data Table 4 Funding Source:* Search Organizations

Boston Medical Center

Program code:

NIH Grant Information (for NIH funded Trials)

Is this trial funded by an NCI grant?* ◉ Yes ○ No

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program
-Select-	-Select-	Enter serial number...	-Select-

+ Add

Grant is Required

Trial Status

Status Date	Status	Comment	Why Study Stopped
	-Select a Trial Status-		

+ Add

Status Date	Status	Comment	Why Study Stopped	Errors/Warnings
08-Jun-2016	In Review	Lorem ipsum dolor sit amet, consectetur adipiscing elit. Sed a ligula urna. Proin felis ex, interdum feugiat sodales ut, sodales a mauris. Donec molestie, quam vitae dapibus pellentesque, nisi augue hendrerit ligula, non vulputate neque ex eu metus nullam.		

Trial Dates

Trial Start Date:* 08-Jun-2016 ◉ Actual ○ Anticipated

Primary Completion Date:* 08-Jun-2016 ◉ Actual ○ Anticipated

Completion Date:* 08-Jun-2016 ○ Actual ◉ Anticipated

FDA IND/IDE Information for applicable trials

Does this trial have an associated IND/IDE?:* ◉ Yes ○ No

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program Code (if applicable)
-Select-		-Select-	-Select-	-Select-

+ Add

IND/IDE is Required

Regulatory Information

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov:

Responsible Party: -Select a Responsible Party-

Trial Oversight Authority: Country | Organization | -Select a Country- | -Select an Organization- | + Add

FDA Regulated Intervention Indicator: ○ No ○ Yes ◉ N/A

Section 801 Indicator: ○ No ○ Yes ◉ N/A

Data Monitoring Committee Appointed Indicator: ○ No ○ Yes ◉ N/A

Trial Related Documents

Protocol Document:* Choose File | No file chosen
Protocol Document is Required

1Sample.pdf

Change Memo Document:* Choose File | No file chosen
Either Change Memo Document or Protocol Highlighted Document is Required

Protocol Highlighted Document:* Choose File | No file chosen
Either Change Memo Document or Protocol Highlighted Document is Required

IRB Approval:* Choose File | No file chosen
IRB Approval is Required

1Sample.pdf

List of Participating Sites: Choose File | No file chosen

Other: Choose File | No file chosen

Describe other document

+ Add More ...

Created By: ctrptrialsubmitter3 (08-Jun-2016 16:05)

Updated By: ctrptrialsubmitter3 (08-Jun-2016 16:05)

Reset | Review

NIH NATIONAL CANCER INSTITUTE
Clinical Trials Reporting Program

Welcome, ctrptrialsubmitter3 | Sign Out
Role: trial-submitter

Write Mode: On

Successfully logged out
Success

Home | Dashboards | Organizations | Persons | Trials | Accrual | Administrative

Home / Search Trials / Register Trial

Register Trial

− Collapse All

Trial Identifiers

Study Source:* National

Lead Organization Trial Identifier:*
Lead Organization Trial Identifier is Required

Other Trial Identifier: Protocol ID Type | Protocol ID
-Select a Protocol ID T | + Add

Trial Details

Official Title:*
Official Title is Required

Phase:* -Select a Phase-
Phase is Required

Pilot?* No Yes

Research Category:* -Select a Research Category-
Research Category is Required

Primary Purpose:* -Select a Primary Purpose-
Primary Purpose is Required

Secondary Purpose: -Select a Secondary Purpose-

Accrual Disease Terminology:* -Select an Accrual Disease Terminology-
Accrual Disease Terminology is Required

Lead Organization/Principal Investigator

Lead Organization:* Search Organizations
Lead Organization is Required

Principal Investigator:* Search Persons
Principal Investigator is Required

Sponsor

Sponsor:* Search Organizations
Sponsor is Required

Data Table 4 Information

Data Table 4 Funding Source:* Search Organizations
Funding Source is Required

Program code:

NIH Grant Information (for NIH funded Trials)

Is this trial funded by an NCI grant?* Yes No

Trial Status

Status Date | Status | Comment | Why Study Stopped
| -Select a Trial Status- | | | + Add

Trial Status is Required

Trial Dates

Trial Start Date:* Actual Anticipated
Trial Start Date is Required
Trial Start Date Type is Required

Primary Completion Date:* Actual Anticipated
Primary Completion Date is Required
Primary Completion Date Type is Required

Completion Date:* Actual Anticipated
Completion Date is Required
Completion Date Type is Required

FDA IND/IDE Information for applicable trials

Does this trial have an associated IND/IDE?:* Yes No

Regulatory Information

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov:

Responsible Party: -Select a Responsible Party-

Trial Oversight Authority: Country | Organization
-Select a Country- | -Select an Organization- | + Add

FDA Regulated Intervention Indicator: No Yes N/A

Section 801 Indicator: No Yes N/A

Data Monitoring Committee Appointed Indicator: No Yes N/A

Trial Related Documents

Protocol Document:* Choose File No file chosen
Protocol Document is Required

IRB Approval:* Choose File No file chosen
IRB Approval is Required

List of Participating Sites: Choose File No file chosen

Informed Consent Document: Choose File No file chosen

Other: Choose File No file chosen
Describe other document

+ Add More ...

Reset | Review | Save as Draft

NCI Trial ID: NCI-2016-00001
Trial Overview
Trial Identification
Trial History
Trial Milestones
On Hold Info
View TSR
Assign Ownership
Check Out History
Email Logs
Admin Data
General Trial Details
Regulatory Information - FDAAA
Regulatory Information - Human Subject Safety
Regulatory Information - IND/IDE
Trial Status
Trial Funding
Participating Sites
Collaborators
Trial Related Documents
NCI Specific Information
Scientific Data
Trial Design
Trial Description
Interventions
Arms/Groups
Eligibility Criteria
Associated Trials
Diseases/Conditions
Data Table 4 Anatomic Sites
Outcome Measures
Sub-Groups Stratification
Biomarkers
Complete

Trial Overview (NCI Trial ID: NCI-2016-00001)

REST Trial Test

NCI ID: NCI-2016-00001
NCT ID: NCT1111111111
Lead Organization Trial ID: REST00006
Lead Organization: AAA test org for test accounts 3
Submission Method: REST Service
Amendment Number:
Amendment Date:

Principal Investigator: Diane Roulston
Clinical Research Category: Interventional
Last Submitter: ctepservice
Last Submitter Organization: CTEP
Last Updated By: ctepservice
Last Updated Date: 08-Jun-2016 15:54

Information Source: Protocol
Current Trial Status: In Review
Current Trial Status Date: 15-Jul-2014
Processing Status: Submitted
Checked Out for Admin. Use by: ctrpabstractor3
Checked Out for Scientific. Use by: ctrpabstractor3

← Back to Search Results | Admin Check In | Scientific Check In | Admin/Scientific Check In

FDA IND/IDE Information for applicable trials

FDA IND/IDE

Does this trial have an associated IND/IDE?:* (•) Yes ( ) No

IND/IDE Information

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program (if applicable)	
-Select-		-Select-	-Select-	-Select-	+ Add

IND/IDE Type is Required
IND/IDE Number is Required
IND/IDE Grantor Type is Required
IND/IDE Holder Type is Required

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program (if applicable)	Delete
ind	111111	CDER	NIH		
ide	222222	CDRH	NCI	CCR	
IND	wewq	CDER	Investigator		

✖ Reset | Save